



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,323	09/28/2000	Henry A. Lardy	HOLISED.063A	2363

26551 7590 06/06/2003

HOLLIS-EDEN PHARMACEUTICALS, INC.
4435 EASTGATE MALL
SUITE 400
SAN DIEGO, CA 92121

EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 06/06/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/675,323	LARDY ET AL.
	Examiner	Art Unit
	Elli Peselev	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 April 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 33-52 is/are pending in the application.

4a) Of the above claim(s) 33-39 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 40-52 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

Newly submitted claims 33-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The inventions are distinct, each from the other because of the following reasons:

Claims 33-39 are directed to compositions while the invention originally claimed is directed to the method of treatment.

Inventions I (claims 33-39) and II (claims 40-52) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as in modulating an immune system (WO 94/03176).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The disclosure is objected to because of the following informalities: In the Examples on page 80 of the specification, figures are mentioned, however, no figures were filed with the present application. Also, the section "Brief Description of the Drawings" is missing.

Appropriate correction is required.

Claims 40-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of prostate cancer or breast cancer with compounds 0-22 as set forth on page 78 of the specification, does not reasonably provide enablement for the treatment or prevention of all androgen responsive diseases such as alopecia, acne, hypogonadism and hirsutism and for prevention of benign prostatic hyperplasia, prostate cancer or breast cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's arguments filed April 17, 2003 have been considered but have not been found persuasive.

The term "prevent" encompasses treating healthy patients and preventing the same from ever getting an androgen responsive disease. Since there is no known method for preventing an androgen related disease such as cancer or alopecia, there is a good reason to doubt that the claimed methods are effective in prevention of any disease.

The treatment and prevention of androgen responsive diseases remains highly unpredictable, and no examples exists for the efficacy of a single compound for the prevention and treatment off androgen responsive diseases generally.

The instant claims encompasses a large number of compounds which possess major differences in structural formula, while applicant presents data for only 23 structurally related compounds (pages 77-81 of the specification). For example, no

compounds were tested wherein R5 or R6 is a phosphonoester, oligosaccharide or a nucleoside. Note, the data on the 23 compounds presented shows that the compounds have different activities.

Furthermore, applicant has provided no guidance or working examples teaching one skilled in the art how to determine which of the countless products used in the claims would be effective in prevention or treatment against which androgen responsive diseases.

Based on the unpredictable nature of the invention, the lack of guidance and the limited working examples, and the extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

Claims 40-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-52 are improper in that the same depend from the non-elected claims 33-38. (Note also, that there is no antecedent basis for compounds of claims 34-38 in claim 33 i.e. in the compounds of claims 34-38 one of R5 or R6 is hydrogen).

Claims 40-52 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the International Patent WO 97/37662 or Neumann (U.S. Patent No. 4,310,523).

Each of the International Patent and Neumann discloses the treatment of androgen responsive disease with an androgen derivative. The claimed methods are anticipated by the International Patent or Neumann. In addition, if there are any

differences between the claimed methods and the prior art methods, the differences would appear to be minor in nature and the claimed methods, which fall within the scope of the prior art's disclosure, would have been *prima facie* obvious from the said prior art's disclosure to a person having ordinary skill in the art at the time the instant invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is 703-308-4616. The examiner can normally be reached on weekdays 8.30 a.m. - 5.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Elli Peselev
June 5, 2003

Elli Peselev
ELLI PESELEV
PRIMARY EXAMINER
GROUP 1800